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NASA Procedural Requirements

NPR 8900.1

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COMPLIANCE IS MANDATORY

Health and Medical Requirements for Human Space Exploration

Responsible Office: Office of the Chief Health & Medical Officer

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Preface

P.1 Purpose

- a. This document provides the procedural requirements and processes for the NASA Health and Medical Program for Human Space Exploration (NPD 8900.5).
- b. NASA shall fulfill all requirements of this NASA Procedural Requirements (NPR) to protect the health and safety of crewmembers involved in space flight activities to enable successful human space exploration.

P.2 Applicability

- a. The requirements in this NPR shall apply to all space exploration activities involving crewmembers, and includes, but is not limited to, space systems, space suits, planetary habitats, planetary rovers, and surface vehicles.
- b. The requirements in this NPR shall apply to internationally provided space systems as documented in distinct separate agreements, such as joint or multilateral agreements.
- c. The requirements in this NPR shall be made applicable to contractors only through contract clauses, specifications, or statements of work in conformance with the NASA Federal Acquisition Regulation Supplement (NFS) and not as direct instructions to contractors.
- d. The requirements in this NPR shall supplement requirements imposed by other Federal Government agencies.
- e. In this NPR, a requirement is identified by "shall" and descriptive material by "is."

P.3 Authority

- a. 42 U.S.C. 2473 (c) (1), Section 203 (c) (1) of the National Aeronautics and Space Act of 1958, as amended.
- b. NPD 1000.0, NASA Governance and Strategic Management.
- c. NPD 1000.3, The NASA Organization.
- d. NPD 8900.5, NASA Health and Medical Policy for Human Space Exploration.

P.4 Applicable Documents

- a. NPR 1382.1, NASA Privacy Procedural Requirements.
- b. NPR 1441.1, NASA Records Retention Schedules.
- c. NASA-STD-3001, NASA Space Flight Human System Standard, Volume 1 - Crew Health.

d. NASA-STD-3000, Volumes I-II, Man-Systems Integration Standards.

e. OCHMO 80771201MED, NASA Crewmembers Medical Standards, Volume 1 - Selection and Periodic Certification.

P.5 Measurement And Verification

P.5.1 Measurements of compliance for this NPR is determined by whether operational managers adhere to the requirements and follow the processes specified in this NPR. The Chief Health and Medical Officer (CHMO) through Agency authority and its Health and Medical Technical Authority (HMTA) function will monitor compliance. This will include appropriate reviews by, and reporting to, the CHMO.

P.6 Cancellation

None.

/S/

Dr. Richard S. Williams

NASA Chief Health and Medical Officer

Chapter 1. Institutional and Programmatic Health and Medical Requirements and Responsibilities for Human Space Exploration

1.1 Overview

1.1.1 As stated in NPD 8900.5, NASA Health and Medical Policy for Human Space Exploration, it is NASA policy to provide a safe and healthy environment for crewmembers, including provision of health and medical care systems, programs, and countermeasures for all mission phases; establishment of health and medical, habitability, and environmental standards; and sponsorship of health-related and clinical research.

1.1.2 The policies for NASA medical operations and astronaut care are provided in NPD 8900.1, NASA Medical Operations Responsibilities in Support of Human Space Flight, and NPD 8900.3, Astronaut Medical and Dental Observation Study and Care Program.

1.1.3 The policy for protection of human research subjects is provided in NPD 7100.8, Protection of Human Research Subjects.

1.2 NASA Health and Medical Standards for Human Space Exploration

1.2.1 NASA health and medical standards for human space exploration shall be established according to the process presented in Appendix C.

1.2.2 Health and medical standards shall be established and documented as follows:

a. Standards that address health and medical screening, evaluation, and certification of crewmembers will be established and documented in OCHMO 80771201MED, NASA Crewmember Medical Standards.

b. Standards that address crewmember health and behavioral health maintenance, preventive programs, space permissible exposure limits (SPELs), permissible outcome limits (POLs), and fitness for duty (FFD) will be established and documented in NASA-STD-3001, NASA Space Flight Human System Standard, Volume 1 - Crew Health.

c. Standards that address medical levels of care for all human space flight programs will be established and documented in NASA-STD-3001, NASA Space Flight Human System Standard, Volume 1 - Crew Health.

d. Current standards that address habitability and environmental health, including atmospheric composition and pressure, air and water quality and monitoring, acceleration, acoustics, vibration, radiation, thermal environment, combined environmental effects, and human factors, are documented in NASA-STD-3000, Volumes I-II, Man-Systems Integration Standards.

1.2.3 The health and medical standards described in 1.2.2 shall apply to all NASA human space flight programs.

1.2.4 Management and Privacy of Medical Information.

- a. Collection, control of records, communications, and public release of all astronaut medical care, biomedical, and medical research data shall comply with the privacy requirements of NPR 1382.1 and the provisions of the Privacy Act of 1974, as amended.
- b. Records will be disposed of in accordance with NPR 1441.1.

1.3 Institutional Roles and Responsibilities

1.3.1 General

- a. The roles and responsibilities of senior management are defined in part in NPD 1000.0, NASA Governance and Strategic Management, and NPD 1000.3, The NASA Organization. NPD 8900.5, NASA Health and Medical Policy for Human Space Exploration, defines explicit health and medical responsibilities for human space exploration; and NPR 7120.5, NASA Space Flight Program and Project Management Requirements; NPD 7120.4, Program/Project Management Policies; and other NASA directives define the explicit program/project management responsibilities of program and project managers. This NPR establishes health and medical processes for human space flight and the responsibilities for their implementation.
- b. The NASA CHMO shall serve as the Office of Primary Responsibility providing leadership, policy direction, assessment, and coordination of the technical requirements and process compliance verification for this NPR.

1.3.2 The CHMO shall be responsible for:

- a. Promulgating health and medical policy.
- b. Serving as NASA independent HMTA.
- c. Establishing and maintaining mission-specific human health and medical standards for space flight.
- d. Reviewing and approving all human health-related and medical requirements for space exploration.
- e. Reviewing and approving all human health-related research requirements and deliverables.
- f. Approving operational implementation of research deliverables that enable human space exploration.
- g. Approving operational use of health and medical systems and technologies prior to their use in space exploration.
- h. Consulting with the Science Mission Directorate (SMD) to ensure that human health and medical-related planetary protection requirements for space exploration are coordinated with existing health and medical policy for human space exploration.

1.3.3 The Exploration Systems Mission Directorate (ESMD) shall be responsible for:

- a. Formulating human health-related and medical requirements that meet Agency-level human system standards.
- b. Defining, planning, conducting, and overseeing NASA-sponsored, human health-related research

and technology development.

c. Developing human health-related research and technology deliverables to an appropriate stage of readiness level for final review, approval, and implementation.

1.3.4 The Space Operations Mission Directorate (SOMD) shall be responsible for:

a. Designating a senior manager for space crew health and safety to advise the Associate Administrator (AA) for SOMD on crew health and medical issues.

b. Recommending requirements for space medicine and countermeasures and proposing milestones for deliverables.

c. Providing on-orbit resources necessary to meet these milestones.

d. Recommending policies applicable to crew health and medical matters.

e. Reviewing space medicine operations and results on a periodic basis.

f. Collaborating with the ESMD regarding health care research-related issues, as appropriate.

g. Overseeing the implementation of health-related research products and deliverables once approved.

1.3.5 The SMD shall be responsible for:

Coordinating with the CHMO regarding health and medical issues related to planetary protection for human space exploration.

1.3.6 In compliance with the established health and medical standards described in section 1.2.2, the Johnson Space Center (JSC) shall be responsible for:

a. Concurring with the NASA HMTA appointment of a JSC Chief Medical Officer (CMO) to exercise health and medical technical authority for activities conducted at that Center and providing a JSC HMTA Implementation Plan, as described in section 1.4 of this NPR and NPR 7120.5, NASA Space Flight Program and Project Management Requirements.

b. Assurance by the JSC CMO that NASA programs and projects resident at the JSC are in compliance with established health and medical standards through the process specified in the JSC Health and HMTA Implementation Plan.

c. Providing recommendations for health and medical, environmental, and human factors standards and requirements. Note: Other Centers may also recommend such standards and requirements.

d. Medically screening, evaluating, and certifying crewmembers.

e. Conducting clinical evaluations and monitoring of astronaut health at regular intervals to determine medical status during ground-based training and space flight.

f. Providing medical care to maintain the crewmember's ability to perform assigned duties before, during, and after space flight.

g. Providing health maintenance and preventive care to maintain the crewmember's ability to perform assigned duties before, during, and after space flight.

h. Providing postflight health rehabilitation to assist the astronaut to return to functional baselines in the areas of physical fitness and physiological and behavioral health.

- i. Providing mission-specific medical and behavioral health training for crewmembers.
- j. Providing programs aimed at maintaining the health status and performance of crewmembers to enable the ability to function and perform all assigned duties over the duration of their career as an astronaut.
- k. Establishing, implementing, and updating a program of preventative medicine based on research findings, health and medical lessons-learned, current standards of medical practice, risk management data (health effects), and expert recommendations.
- l. Developing and managing the Longitudinal Study of Astronaut Health.
- m. Conducting spacecraft and habitat environmental health evaluations to certify compliance with environmental health requirements.

1.4 NASA Health and Medical Technical Authority

1.4.1 The CHMO shall serve as Agency HMTA as authorized by NPD 1000.0, NASA Governance and Strategic Management, and NPD 8900.5, NASA Health and Medical Policy for Human Space Exploration; and as described in NPR 7120.5, NASA Space Flight Program and Project Management Requirements.

1.4.2 The NASA CHMO provides overall leadership of the health and medical technical authority process for space flight programs/projects, including Agency health and medical policy direction, requirements, and standards. The NASA CHMO hears appeals of the Center HMTA decisions when they cannot be resolved at lower levels.

1.4.3 The HMTA shall assure that programs and projects comply with Agency health and medical requirements at identified milestone decision points, and shall certify that programs and projects comply with Agency health and medical requirements prior to space flight missions.

1.4.4 The NASA CHMO shall implement HMTA at applicable NASA Centers.

1.4.5 For applicable NASA Centers, the NASA CHMO appoints, with the concurrence of the NASA Center Director, a Center CMO who shall exercise health and medical technical authority for that Center.

1.4.6 Applicable NASA Centers shall develop a HMTA Implementation Plan to execute technical authority with organizational separation of health and medical technical authority from programs and projects.

- a. The CMO shall be responsible for HMTA implementation.
- b. The Center CMO shall ensure that qualified discipline expertise is engaged to support programs and projects and shall establish appropriate delegations of authority to efficiently support program and project day-to-day operations with the concurrence of the NASA Chief Health and Medical Officer.
- c. The Center CMO shall be responsible for approving changes to, and waivers of, all HMTA-owned requirements. The HMTA is responsible for assuring that changes to, and waivers of, technical requirements are submitted to and acted on by the appropriate level of HMTA.
- d. The Center CMO shall disposition appeals of standards and requirements and report to the NASA CHMO.

1.4.7 Clinical decision making shall continue in accordance with the NASA Medical Policy Board (MPB) and Aerospace Medicine Board (AMB) responsibilities specified in NPD 1000.3, The NASA Organization.

1.4.8 Unresolved health and medical issues within a team will be elevated to achieve resolution at the appropriate level. At the discretion of the dissenting person(s), a decision may be appealed to the next higher level of management for resolution. Dissenting opinions raised by the HMTA are handled by the process set forth in NPR 7120.5D, NASA Space Flight Program and Project Management Requirements.

Chapter 2. Human Health-Related System Design Requirements

2.1 System Design Requirements Definition

2.1.1 Program Managers shall formulate human health-related system design requirements in compliance with NASA-STD-3001, NASA Space Flight Human System Standard, Volume 1, and NASA-STD-3000, Volumes I-II, Man-Systems Integration Standards.

2.1.2 The NASA HMTA shall approve all human health-related system design requirements.

2.2 System Design Requirements

2.2.1 The space system shall provide the following systems and capabilities in compliance with NASA-STD-3001, NASA Space Flight Human System Standard, Volume 1, and NASA-STD-3000, Volumes I-II, Man-Systems Integration Standards:

- a. Diagnostic and treatment systems in compliance with established level of medical care standards.
- b. Capability for medical services to support all phases of a mission in compliance with established level of medical care standards.
- c. Health maintenance, preventive, and countermeasure systems in compliance with established space flight crew health standards.
- d. Medical communications, consistent with privacy requirements and the Privacy Act of 1974, and established level of medical care and space flight crew health standards.
- e. A healthy and safe environment in compliance with established habitability and environmental health standards.
- f. System implementations that meet established human performance and constraints related to human health.

Chapter 3. Human Health-Related Research and Technology

3.1 Requirements Definition

3.1.1 The ESMD shall develop and recommend human health-related research and technology development requirements.

3.1.2 The HMTA shall review and approve, with modifications as needed, all proposed health-related research and technology development requirements.

3.1.3 The HMTA shall review and assess the progress of human health-related research and technology development programs against established health and medical standards.

3.2 Operational Implementation

The HMTA shall approve, approve with revision, defer, or reject, as necessary, all health-related research deliverables and contractor health and medical technology and systems deliverables prior to implementation by the appropriate operational community.

Appendix A. Definitions

A.1 Fitness for Duty (FFD) Standards: The minimum measurable capability or capacity for a given physiological or behavioral parameter that allows successful performance of all required duties. A functional capacity is measured.

A.2 Health: The physiological, psychological, and dental status and well-being of an individual.

A.3 Level of Care: The amount and type of care one will render based on perceived need and ability.

A.4 Medical: The care and treatment of an individual for illness or injury.

A.5 Permissible Outcome Limits (POL): An acceptable maximum decrement or change in physiological or behavioral parameter, as the result of exposure to the space environment. A biological/clinical parameter is measured.

A.6 Planetary Protection: Policies, requirements, and procedures designed to prevent biological contamination of other solar system bodies that might jeopardize scientific investigations on the origins and evolution of life, as well as to prevent the potential for harmful contamination of the Earth by extraterrestrial materials carried on board returning spacecraft.

A.7 Space Permissible Exposure Limits (SPEL): The quantifiable limit of exposure to a space flight factor over a given length of time. A physical/chemical agent is being measured.

A.8 Standard of Care: The benchmark by which an established level of care is provided.

A.9 Transition to Medical Practice (TMP): An assessment of the effectiveness and operational readiness of medical research and technology products and deliverables. TMP provides a clear channel for human health and medical-related flight and ground research results for transition to tools available to support Agency human space flight programs.

Appendix B. Acronyms

AMB	Aerospace Medicine Board
CCB	Configuration Control Board
CMO	Chief Medical Officer
CHMO	Chief Health and Medical Officer
ESMD	Exploration Systems Mission Directorate
FFD	Fitness for Duty
HMTA	Health and Medical Technical Authority
JSC	Johnson Space Center
MPB	Medical Policy Board
NFS	NASA Federal Acquisition Regulation Supplement
OCHMO	Office of the Chief Health and Medical Officer
POL	Permissible Outcome Limits
TMP	Transition to Medical Practice
SLSD	Space Life Sciences Directorate
SMD	Science Mission Directorate
SOMD	Space Operations Mission Directorate
SPEL	Space Permissible Exposure Limits

Appendix C. Process for Establishing Health and Medical Standards

Standard Setting Process:

Health and medical standards are initiated by the NASA CHMO and are developed under the supervision of the delegated HMTA with participation of other Centers and external experts, as appropriate. Final approval is executed by the NASA CHMO.

Health and medical standards are established by the OCHMO per the following process:

- a. A recommendation for development of a new standard or revision of an existing standard may originate anywhere in the Agency, such as in the OCHMO, the SOMD, the ESMD, the AMB, or the Space Life Sciences Directorate (SLSD) at JSC, and is forwarded to the NASA CHMO for consideration.
- b. The NASA CHMO reviews the recommendations, and if warranted, initiates development or revision of a standard and establishes a standards development team under the supervision of the delegated HMTA. Note: The standards development team includes internal NASA experts and may include external discipline experts, as appropriate.
- c. The standards development team drafts the standard which is reviewed according to the process established by the delegated HMTA with the concurrence of the NASA CHMO.
- d. The delegated HMTA then reviews the draft standard and provides a recommendation for approval of the new or revised standard to the NASA CHMO.
- e. The NASA CHMO determines whether or not independent technical review of the draft standard is required by an external team and convenes a team to conduct the review, where appropriate.
- f. The draft/revised standards are distributed to affected and interested parties (e.g., Flight Crew Operations Directorate/Astronaut Office, mission directorates, functional staff offices, Centers, etc.) for review and comment.
- g. The draft/revised standards are presented to the NASA MPB, which provides a recommendation for approval to the NASA CHMO.
- h. The NASA CHMO considers comments and recommendations, and either rejects, recommends further modifications, or executes final approval of the standard.
- i. Implementation of the standards is overseen by the delegated HMTA.
- j. Periodic review of the standards occurs every five years, or at more frequent intervals if new data or clinical observations indicate that a standard or standards need to be updated.

Appendix D. Transition to Medical Practice

Note: The Transition to Medical Practice (TMP) review process is designed to assess the effectiveness and operational readiness of human health-related research and technology products and deliverables. It provides a clear channel for human health and medical-related flight and ground research results for transition to tools available to support Agency human space flight programs.

The TMP review process shall be conducted according to the HMTA established below and applied to newly proposed medical procedures, practices, processes, countermeasures, or technologies resulting from NASA-sponsored research that are designed to maintain the health, and/or support the medical care, of space flight crews.

1. The submitting organization presents a proposal for TMP review of a research or technology deliverable or product to the appropriate JSC configuration control board (CCB) for review and recommendation to the JSC CMO.
2. Upon recommendation by a JSC CCB, the submitting organization provides a written request for TMP review of a research or technology deliverable or product to the JSC CMO for review.
3. The JSC CMO recommends to the NASA CHMO that a panel be convened.
4. A panel is convened to review each deliverable or product. Review panel members will have the appropriate aerospace medicine and operational expertise and will include representation from the AMB.
5. The submitting organization provides the following documentation to the JSC CMO and the NASA CHMO in advance of the TMP panel review:
 - (1) A detailed description of the deliverable or product, its intended use or application, and a description of how the deliverable or product addresses a NASA-identified critical risk, medical issue, or application.
 - (2) Data demonstrating the efficacy, effectiveness, or utility of the deliverable or product.
 - (3) Data demonstrating the operational validation of the deliverable or product.
 - (4) An implementation plan of how the product or deliverable is to be used or applied (e.g., protocol, dosing regime, scope of use, etc.).
 - (5) An analysis of the mission resources (e.g., crew time, volume, power, etc.) necessary to implement the product or deliverable.
6. The TMP panel provides a recommendation for consideration by the JSC CMO and the NASA CHMO.
7. The NASA CHMO provides recommendations to the MPB for final consideration and approval.
8. The MPB shall provide one of the following recommendations:
 - * Approve: The CHMO will certify the product or deliverable for NASA medical practice.
 - * Approve with Revision: The CHMO will certify the product or deliverable as NASA medical practice, with revisions to the implementation plan or scope of use, as recommended by the TMP review panel.

* Defer: A decision regarding the product or deliverable will be deferred until additional information can be supplied to the review panel. This may be a request for additional supporting documentation or for additional data collection and/or experimentation.

* Reject: The product or deliverable will not be certified as NASA medical practice.

9. The OCHMO shall convey, in writing, the results of the TMP review to the submitting organization and to the JSC CMO.

10. Once approved, the product or deliverable will be available for use according to established NASA policy.

Appendix E. References

- a. NPD 1080.1, NASA Science Policy.
- b. NPD 1800.2, NASA Occupational Health Program.
- c. NPD 7100.8, Protection of Human Research Subjects.
- d. NPD 7120.4, Program/Project Management.
- e. NPR 7120.5, NASA Space Flight Program and Project Management Requirements.
- f. NPD 8020.7, Biological Contamination Control for Outbound and Inbound Planetary Spacecraft.
- g. NPD 8070.6, Technical Standards.
- h. NPD 8700.1, NASA Policy for Safety and Mission Success.
- i. NPR 8705.2, Human-Rating Requirements for Space Systems.
- j. NPD 8900.1, NASA Medical Operations Responsibilities in Support of Human Space.
- k. NPD 8900.3, Astronaut Medical and Dental Observation Study and Care Program.